**IN THE UNITED STATES DISTRICT COURT**
**FOR THE DISTRICT OF NEW JERSEY**
**CAMDEN VICINAGE**

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| IN RE VALSARTAN, LOSARTAN, AND IRBESARTAN PRODUCTS LIABILITY LITIGATION<br><br>This document relates to:<br>*All Actions* | No. 1:19-md-2875-RBK<br><br>Hon. Robert B. Kugler<br>Hon. Thomas I. Vanaskie |

**PLAINTIFFS' MEMORANDUM OF LAW IN OPPOSITION TO TEVA'S MOTION TO SEAL**

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## I. INTRODUCTION

Over the course of nearly a dozen weeks, Plaintiffs cooperatively engaged in meet-and-confers with each of the Manufacturer Defendants regarding the confidentiality designations of hundreds of documents and depositions appended to the Parties' Class Certification Briefing. During these meet-and-confers, Plaintiffs heeded previous admonitions from the Court and endeavored to provide reasonable redactions when such redactions were appropriate, or to concede when documents were legitimately confidential and would cause cognizable, real and material harm to a Defendant should it be filed publicly on the docket. The result of these efforts limited the entire universe of dispute with Defendants to these six (6) documents produced by Teva. However, with respect to these six documents, Plaintiffs cannot and will not concede they are entitled to sealing treatment (in whole or in part).

The six documents at issue relate primarily to investigative activities conducted by Teva after the nitrosamine impurity became public. They include documents related to Teva's high level investigation into the root cause of the nitrosamine contamination, Teva's toxicological assessment of the nitrosamine contamination, and Teva's investigations and assessments of its Valsartan API suppliers who supplied API contaminated with the nitrosamine contamination. As more fully discussed below, each of these activities falls squarely within the framework of the current Good Manufacturing Practices (hereafter "cGMPs"),

which are common, industry-wide practices utilized by every single manufacturer[1] of a drug substance – and the exact opposite of commercially sensitive information that is somehow proprietary only to Teva.

The self-serving and broad attestations contained in the Declaration of Anthony Binsol (hereafter "Binsol Decl.") do not meet the burden required by the Third Circuit to maintain sealing. Teva's motion should be denied.

## II. LEGAL STANDARD

### a. Judicial Documents Are Presumptively Entitled to Public Access

As the Third Circuit has repeatedly held, judicial documents, such as the documents appended in support of (or in opposition to) the overall class certification briefing, are entitled to a presumption of public access. *In re Avandia Mktg., Sales Practices & Prods. Liab. Litig.*, 924 F.3d 662, 672 (3d Cir. 2019). As the Court held, "the more rigorous common law right of access [applies] when discovery materials are filed as court documents." *Id.*

While Rule 26 permits the use of protective orders to designate these documents as confidential when produced during discovery, the standard is different than the inquiry a Court must engage in prior to sealing the same documents when they become judicial documents. The public right of access—unlike a Rule 26

[1] It bears noting that documents exactly like the ones in dispute here were likewise challenged with the other Manufacturer Defendants, and those Defendants agreed with Plaintiffs that the documents did not require full sealing.

inquiry—begins with a presumption in favor of public access. *Avandia*, 924 F.3d at 670; *see also* D.E. 1269, p. 7.

This is especially true here, in assessing judicial documents that are being offered in support of the proposed certification of a class action. The Third Circuit has previously held that the right of public access is particularly compelling in class cases because "many members of the "public" are also plaintiffs in the class action*"* *Goldstein v. Forbes (In re Cendant Corp.)*, 260 F.3d 183, 193 (3d Cir. 2001). Allowing the right to access judicial documents (such as those appended to the Class Plaintiffs' Motions), promotes confidence in the "administration" of the Class Members' case. *Id.*

**b. <u>The Proponent of Sealing Must Make a Specific Showing of Harm to Overcome Presumption of Public Access</u>**

Because there is a presumption in favor of access for these judicial documents, the burden requires Teva to demonstrate that the "material is the kind of information that courts will protect, and that disclosure will work a clearly defined and serious injury to the party seeking closure." *In re Avandia Mktg., Sales Practices & Prods. Liab. Litig.*, 924 F.3d 662, 678 (3d Cir. 2019) (quoting *Miller v. Ind. Hosp.*, 16 F.3d 549, 551 (3d Cir. 1994)).

i. **Commercially Sensitive Information Is Not Categorically Exempt from Public Access**

While certain trade secrets or highly commercially sensitive information may overcome the public right of access, that is not to say that trade secrets or confidential commercial information are entitled to an "absolute exception" from public access. *Cole's Wexford Hotel, Inc. v. Highmark, Inc.*, No. 2:10-cv-01609-JFC, 2019 U.S. Dist. LEXIS 142214, at *37 (W.D. Pa. May 31, 2019). Furthermore, merely confidential business information is not entitled to the same level of protection from disclosure as trade secret information. *Littlejohn v. BIC Corp.*, 851 F.2d 673, 685 (3d Cir. 1988).

Additionally, not all commercial harms or financial losses are entitled to protection from disclosure. These includes potential commercial harms that might stem from embarrassment and injury to corporate reputation (*Avandia*, 924 F.3d 662, 672), or information that may cause the value of stock to decline does not override public access (*Littlejohn*, 851 F.2d at 685), or even information related to poor corporate management (*Publicker Indus., Inc. v. Cohen*, 733 F.2d 1059, 1074 (3d Cir. 1984)).

ii. **The Proponent of Sealing Must Articulate Specified Harm**

In terms of the articulated compelling and countervailing interests against disclosure, "specificity is essential." *Avandia*, 924 F.3d at 673 (quoting *In re*

*Cendant Corp.*, 260 F.3d at 194). "Broad allegations of harm, bereft of specific examples or articulated reasoning, are insufficient." *Id.*

Moreover, the Court has already rejected affidavits proffered in this case that contain conclusory and unspecified statements of "harm" in conjunction with the sealing inquiry. *In re Valsartan N-Nitrosodimethylamine (NDMA)*, 512 F. Supp. 3d 546, 553 (D.N.J. 2021). These include conclusory statements regarding generalized "allegations of injury to reputation and client relationships or the embarrassment that might result," or statements that the authors and recipients of the documents expectation that the documents would remain confidential, because "large swatches of routine emails would be kept under wraps." *Id*.

Upon a review of the clearly defined and serious injury, the District Court must articulate the compelling, countervailing interests to be protected, and make "specific findings on the record concerning the effects of disclosure." *Avandia*, 924 F.3d at 672-73 (quoting *In re Cendant Corp.*, 260 F.3d at 194). As such, any affidavit must be analyzed in conjunction with an independent review of the at issue documents, because, as Judge Schneider previously stated, the Court "is not required to give credence to [a] conclusory self-serving affidavit that is inconsistent with the Court's independent review of [the] documents." *In re Valsartan N-Nitrosodimethylamine (NDMA)*, 512 F. Supp. 3d 546, 553 (D.N.J. 2021).

The temporal posture of the parties must also be assessed. As the Third Circuit held in Avandia, "[s]ealing must be based on *current evidence* to show how public dissemination of the pertinent materials *now* would cause the competitive harm." *Id.* at 678 (quoting *In re Cendant Corp.*, 260 F.3d at 196) (emphasis added).

## III. ARGUMENT

### a. The At-Issue Documents Contain No Confidential Information

Plaintiffs were extremely circumspect when negotiating the sealing of the documents appended to the Parties' respective Class Certification motions.[2] The six at-issue documents that Plaintiffs challenge largely fall into three distinct topical groupings:

i) ***formal investigative reports regarding the nitrosamine contamination*** (TEVA-MDL2875-00049024 (Exs. 16 and 67 to D.E. 1748), and TEVA-MDL2875-00549883 (Ex. 66 to D.E. 1748));

ii) ***internal communications and investigations regarding the toxicology of nitrosamine contamination*** (TEVA-MDL2875-00020519 (Ex. 72 to D.E. 1748), and TEVA-MDL2875-00042885 to TEVA-MDL2875-00042887 (Ex. 97 to D.E. 1748)); and

iii) ***internal communications regarding audits of ZHP in the wake of the knowledge of the nitrosamine contamination*** (TEVA-MDL2875-00522655 to TEVA-MDL2875-00522660 (Ex. 88 to D.E. 1748), and

[2] Plaintiffs did not challenge documents which contained information that could potentially be considered a proprietary trade secret (such as documents detailing specific manufacturing processes), or documents which would contain the type of commercial sensitive information the Third Circuit has previously held to be the type that might warrant sealing (such as customer sales data). Plaintiffs likewise provided reasonable proposals for redactions of this information when appropriate. As such, what was initially a universe of over one thousands potentially challenges has been limited to only these 6 documents.

TEVA-MDL2875-00400391[3] to TEVA-MDL2875-0040000 (Ex. 90 to D.E. 1748)).

**i. Teva's Investigation into the NDMA Impurity is Not Commercially Sensitive Information**

Teva claims that the "disclosure of [TEVA-MDL2875-00049024] would cause irreparable harm to Teva by providing its competitors with direct insight into Teva's internal processes for investigating, evaluation, correcting and mitigating the presence of nitrosamine impurities." Binsol Decl. at 4. However, these were not processes and evaluations that Teva decided to conduct on their own -- Teva was required by the FDA to conduct these investigations and evaluations. *See* Ex. A, TEVA-MDL2875-00051242. Moreover, these evaluations were not only conducted by Teva, but they were also conducted by every drug manufacturer across the world who manufactured ARBs.[4]

Additionally, Teva cannot credibly claim that its internal investigations into nitrosamine impurities are somehow commercial sensitive, when a Teva subsidiary

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[3] Plaintiffs are cognizant that they previously challenged the confidentiality designation on this document, but as discussed *supra*, the inquiry related to sealing is a higher bar given the presumption of public access for judicial documents. As such we believe the specific inquiry about sealing must be addressed by the Court. Even if Teva may have met the "good cause standard of Rule 26(c)" this "cannot in itself provide the showing needed to seal the submission of judicial records to be utilized in a formal adjudication of central issues in a lawsuit." *Carnegie Mellon University*, 2013 U.S. Dist. LEXIS 45050, 2013 WL 1336204 at * 4.

[4] *See* Ex. B, https://www.ema.europa.eu/en/documents/referral/nitrosamines-emea-h-a53-1490-assessment-report_en.pdf (last accessed December 19, 2022) (asking manufacturers to conduct a investigation taking into account the relevant ICH Guidance and discussion of the different factors that would go into such an investigation). *See also* Ex. C, https://www.fda.gov/media/141720/download (last accessed December 19, 2022) (requesting that investigations into the root cause of potential nitrosamine impurities should be investigated and identifying changes that would eliminate the root cause).

has an entire public facing website detailing how the company evaluates nitrosamine impurities in its drug products. *See* Ex. D, Teva API Website. There, Teva publicly discusses how it identified potential risks in its products, and then further mapped these risks as either "high, medium, or low risk, based on the proximity between the two components – nitrosating source and amine source – during the production process." *Id.* This information was further elaborated upon in a webinar that Teva invited members of the public (and other competitors from the pharmaceutical industry) to join. *See* Ex. E, Teva Webinar featuring head of global compliance, Lena Ben Moha-Lerman (discussing the potential risks of contaminated starting materials and solvents, such as recycled solvents or materials that we source from a third-party, and how in response to this Teva sends out dedicated questionnaires to all our vendors and based on their answers we conclude whether or not there is a potential risk).

**ii. Teva's Investigation into the Toxicology of NDMA is Not Commercially Sensitive Information**

Much like with the evaluations and investigations that were required to be conducted under cGMPs, Teva's post hoc investigation into the toxicology of the nitrosamine impurities was likewise an investigative process required by world regulators after the discovery of the contamination. In guidance, the FDA requires that a drug substance manufacturer employ established risk management strategies and assess the theoretical increase in risk, which would result in investigative

documents like those which Teva is now claiming in some internal proprietary practice. [5]

Contrary to the assertions contained in Mr. Binsol's declaration, these cancer risk assessments Teva conducted are well "established" throughout the industry (and not some commercially sensitive process proprietary to Teva). *Id.* They are predicated on much of the same information and secondary sources Teva used in their risk assessment.

Nevertheless, Mr. Binsol now claims that publication of this document would provide "direct insight with Teva's internal thought processes concerning a toxicological assessment" and risk assessment of NDMA in Valsartan." Binsol Decl. at 6. However, despite this grave fear, Teva appears to have no problem with the author of TEVA-MDL2875-00020519, Raphael Nudelman, *conducting paid industry talks about this very subject to the public*. *See* Ex. F, Raphael Nudelman list of public speeches (including a speech discussing the setting the acceptable limit on nitrosamines that lack carcinogenicity data, and a speech related to the "best practices" related to computing the mutagenicity of an impurity).

[5] *See* Ex. G (last accessed December 19, 2022) https://www.fda.gov/media/85885/download

### iii. Teva's Investigations into their API Suppliers Are Not Commercially Sensitive Information

While Teva claims that disclosure of communications regarding their audit of ZHP, an API supplier, would cause "irreparable harm to Teva by providing its competitors with internal thought processes of Teva leadership concerning an internal audit as well as Teva's internal reporting processes." However, this auditing and internal reporting of the auditing processes are, again, practices and activities which are part of the activities manufacturers are required to conduct as part of cGMP and not a proprietary activity of Teva. In fact, the FDA provided a fairly detailed presentation on the matter of how to audit a supplier, and which metrics and parameters one would use to qualify a supplier. *See* Ex. H. Moreover, as part of this presentation, the FDA even included a case study from Pfizer (a global pharmaceutical manufacturer that with an even market cap than Defendant Teva), to demonstrate how they went about to develop their supplier management practices and infrastructure. *Id.*

## b. Teva's Declaration Does Not Provide the Specific, Concrete Harm Required by this Court

Mr. Binsol's Declaration is replete with sweeping statements regarding the competitive harm Teva would suffer. However, Mr. Binsol fails to credibly articulate how and why information regarding Teva's compliance (or non-compliance) with public guidelines and regulations regarding cGMPs would actually be competitively harmful. Mr. Binsol's affidavit is further undercut by the fact that

Teva has disclosed much of the information it now claims is competitively sensitive to industry partners in webinars and talks. *See* Exs. C-F.[6]

If the implicit implication in Mr. Binsol's affidavit is that knowledge of Teva's poor management in complying with and abiding by the global regulations and guidance is somehow competitively sensitive, as further discussed *supra*, information about poor management is not enough to overcome the presumption of public access.

## IV. CONCLUSION

For the foregoing reasons, the Court should deny Teva's motion to seal. In accordance with Local Rule 5.3, Plaintiffs' have attached a proposed order to this brief.

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Respectfully Submitted,

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[6] Teva's multiple public webinars about these topics also demonstrates the presence of another important factor which is a critical factor in assessing sealing – the need for information to be disclosed publicly if it involves a matter of public health and would be of great importance to the public. *Avandia*, 924 F.3d at 671. It is obvious Teva views this information as a matter of some public importance – otherwise there would be no market for $400 webinars.

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**CERTIFICATE OF SERVICE**

I hereby certify that on December 19, 2022, a true and correct copy of the foregoing was filed and served upon all counsel via operation of the CM/ECF system for the United States District Court for the District of New Jersey.

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